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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,264	03/12/2004	Don Fishbein	52427-AA/JPW/GJG	8229
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COOPER & DUNHAM, LLP 30 Rockefeller Plaza 20th Floor NEW YORK, NY 10112			EXAMINER HUGHES, ALICIA R	
			ART UNIT	PAPER NUMBER
			1614	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,264	<b>Applicant(s)</b> FISHBEIN, DON	
	<b>Examiner</b> ALICIA R. HUGHES	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims and Examination***

Claims 30-47 are pending and the subject of this Office Action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 November 2009 has been entered.

Applicant's arguments, filed on 02 November 2009, have been fully considered and they are deemed to be persuasive regarding the previous rejection for the reasons set forth below. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

### ***Priority***

Applicants continue to claim priority as early as 05 December 1996, dating back to U.S. Patent Provisional Application No. 60/032,414. However, another review of each of the aforementioned disclosures failed to yield a teaching of the instantly claimed invention, as amended. As a result, for prior art purposes, herein, the filing date of this application, 12 March 2004 is considered the relevant date.

### ***Claim Rejection - 35 U.S.C. §102(a)***

The following is a quotation of 35 U.S.C. 102(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 30, 42-45 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Demling, Robert H., "Oxandrolone Induced Lean Mass Gain During Recovery From Severe Burns Is Maintained After Discontinuation of the Anabolic Steroid," *Burns*, Vol. 29, pages 793-797 (2003)[hereinafter referred to as Demling et al"].

Applicants argument in response to this rejection is that the same fails, because Demling et al is not prior art. For the reasons already made of record, prior and supra, the same remains unpersuasive and thus, the rejection does not fail for want of relevant prior art.

As noted prior. Demling et al teach that "severe catabolism, resulting in rapid loss of lean body mass, is a well-recognized complication of major burns" (Page 793, Col. 1, lines 1-2) and that "providing ... oxandrolone has been shown to significantly increase the rate of restoration of lost body weight and lean mass after burn injury" (Page 793, Col. 1, lines 8-11). Demling et al undertook a study to determine "whether the lean mass and body weight which was regained was maintained 6 months after discontinuation of the oxandrolone" (Page 793, Col. 2, lines 12-15) by studying major burn patients in the recovery phase where attempts to restore lost weight and lean mass are initiated (Page 793, Col. 2, lines 16-19).

Patients in the study were monitored after discharge from an acute burn center for at least one year (Page 794, Col. 1, lines 7-9). The patient population was randomly split into two categories, one receiving optimum nutrition, including protein and exercise and the other receiving optimum nutrition, including protein (Page 795, Figure 2) and exercise supplemented by the administration of oxandrolone (Page 794, Col. 1, lines 11-17; See also page 795, Table 2). In the course of the study, "[b]i-weekly changes in lean body mass were calculated and compared with changes in lean body mass were calculated and compared with changes in body

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weight to determine the percent of weight gain which was lean mass (Page 794, Col. 1, last line through Col. 2, lines 1-3). Body composition and body weight were measured at discharge from rehab and again at 6 month post-discharge for all patients and in for oxandrolone patients, again 6 Months after discontinued use (Page 794, Col. 2, lines 4-10). "Oxandrolone was discontinued once ninety percent of the lost body weight had been restored and the patients were at a level of muscular function which allowed for independent daily living activities (Page 797, Col. 1, lines 6-9).

Table 1 of Demling et al does a comparative analysis of post-burn changes in body weight and demonstrates that in weeks 1, 2, 3, and 4, the body weight of patients treated with oxandrolone more than doubled that of patients not so treated (Page 794, Table 1). Based on the data provided, Demling et al concluded that "[t]here was a significant increase in body weight and lean body mass gain in the group receiving oxandrolone compared to the nutrition alone group at all measurement periods during the acute rehabilitation phase (Page 795, Col. 1, lines 6-9). And importantly, "[a]ll restored LBM ["lean body mass"] was retained" (Page 796, Col. 1, lines 12-13).

Demling et al state conclusively, "the addition of an anabolic steroid increases the rate of restoration of lost body weight and lean mass up to four-fold after burns, trauma, infection and other post-catabolic states ... It is anticipated that lean mass that has been regained remains after discontinuation of the anabolic steroid ..." (Page 796, Col2, lines 4-10). More specifically, "the amount of lean mass gained in both groups during the acute rehabilitation period did not change 6 months after discharge, indicating that the large amount of lean mass gained on oxandrolone was maintained after discontinuation" (Page 797, Col. 1, lines 22-26 and last two lines).

With regard to claim 42, as noted prior and referenced on a previous PTO-892 Form, oxandrolone is an anabolic steroid with numerous synonymous chemical names, including 17 $\beta$ -Hydroxy-17 $\alpha$ -methyl-2-oxa-5 $\alpha$ -androstane-3-one, as disclosed in claim 42 of the present invention. Therefore, oxandrolone as noted by its IUPAC name is met by the disclosure in Demling et al.

In light of the foregoing, claims 30, 42-45 and 47 are clearly anticipated.

***Claim Rejection – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-40 and 46 are rejected under 35 U.S.C. 103(a) as being obvious over Demling et al in view of U.S. Patent No. 6,090,799 [hereinafter referred to as “Berger”]<sup>1</sup>.

The teachings of Demling et al and the arguments associated therewith, *supra*, are incorporated herein by reference in their entirety. Demling et al do not disclose, but rather is silent on the dosage amounts of oxandrolone administered and as well, to routes of administration. The same, however, are taught by Berger.

Berger teaches that “[a]nabolic steroids, as a class, are known to stimulate appetite” (Col. 2, lines 64-65), and furthermore, that oxandrolone, increases protein synthesis (Col. 3, lines 4-5).

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<sup>1</sup> Cited on previous PTO-892 Form.

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Berger also teaches that “[i]mproved nutrition is important to individuals with AIDS who have experienced loss of lean body mass” (Col. 2, lines 65-67). Berger also teaches the administration of oxandrolone, in a daily dosage of about 2.5 milligrams [“mg”] to about 80 mg (Abstract; Col. 2, lines 14-18; Col. 3, lines 30-38; Col. 5, lines 41-49). Through the administration of oxandrolone, “[l]oss in muscle mass (wasting) is attenuated, and body weight can be more readily maintained in this manner ... revers[ing] weight loss” (Col. 2, lines 1-5; see also, the Example at Col. 7, lines 33-57 – Col. 8, lines 1-24). For purposes of examination herein, the Examiner interprets “reversing weight loss” to be equivalent with weight gain.

Berger also teaches that “[o]xandrolone preferably is administered orally; however, other routes of administration can be utilized as well” (Col. 2, lines 8-9). The Berger invention teaches oxandrolone combined with solid or liquid pharmaceutical carriers and formulated using pharmacologically acceptable excipients, or dissolved or suspended in physiologically acceptable solvents or liquid vehicles for oral, percutaneous, or topical administration (Col. 3, lines 19-25). “Examples of suitable unit dosage forms in accordance with this invention are tablets, pills, powder, packets, wafers, cachets, segregated multiples of any of the foregoing, transdermal patches, aliquots of injectables, and like forms” (Col. 4, 35-39).

Though Berger does not teach the use of anabolic steroids in the treatment of burns, one of ordinary skill in the art would be motivated to modify the teachings of Demling et al by the teachings in Berger to arrive at the instant invention, because both references teach patient populations that have experienced attenuated exponential wasting due to catabolism that is reversed by the administration of oxandrolone.

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In light of the foregoing, and absent any evidence to the contrary, one would conclude that it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of oxandrolone, in the dosages and dosage forms disclosed in the present invention, would be an effective method for promoting weight gain after weight loss for one who experiences loss of lean body mass due to burn-induced trauma.

Claims 30 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over Demling et al in view of U.S. Patent No. 5,434,146 [hereinafter referred to as "Labrie et al"].<sup>2</sup>

The teachings of Demling et al, *supra*, are incorporated herein by reference in their entirety. Demling et al do not disclose, but rather is silent on oxandrolone administered in a sustained release formulation. The same, however, is taught by Labrie et al.

Labrie et al teach the administration of certain anabolic steroids, including oxandrolone, in a sustained release formulation (Abstract; Col. 21, lines 17 and 61-68).

One of ordinary skill in the art would be motivated to combine the teachings of Demling et al with the teachings of Labrie et al., due to their overlapping subject matter, most notably the administration of oxandrolone. In view of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of an effective amount of oxandrolone in sustained release formulations would be effective for promoting weight gain after weight loss resulting from burn-induced trauma in a patient.

### **Conclusion**

No claims are allowed.

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<sup>2</sup> Cited on previous PTO-892 Form.



**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like

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assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alicia R. Hughes/

Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614